DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 16, 2014

Yung Sheng Optical Co., Ltd.
Mr. Wen-Han Chen
Regulatory Affairs Supervisor
3F-1, No. 6 Jhongke Road, Daya District
Taichung City 42881 Taiwan

Re: K143052
Trade/Device Name: Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear, Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: October 15, 2014
Received: October 23, 2014

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143052

Device Name
Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear, Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens

Indications for Use *(Describe)*
The Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are indicated for the correction of ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens help protect against transmission of harmful UV radiation to the cornea and into the eye.

For Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear, the eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Submitter: Yung Sheng Optical Co., Ltd.

Address: 3F-1, No.6, Jhongke Road, Daya District, Taichung City 42881 Taiwan
Manufacturer Address No.8, Keya 2nd Road, Daya District, Taichung City 42881, Taiwan
Phone: (04) 25658384 #156~157
Fax: (04) 25658387
Contact: Wen-Han Chen / Tsung-Jen Yeh
Establishment Registration Number: N/A
Date Prepared November 17, 2014

5.3 Identification of the Device:

Proprietary/Trade name: Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens
Common Name: Contact Lens
Classification Name: Lenses, Soft Contact, Daily Wear
Device Classification: II
Regulation Number: 21 CFR 886.5925 (b) (1)
Panel: Ophthalmic
Product Code: LPL for Lenses, Soft Contact, Daily Wear
MVN for Lens, Contact, (Disposable)

5.4 Identification of the Predicate Device:

Predicate Device Name: Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
Manufacturer: Yung Sheng Optical Co., Ltd.
510(k) Number or Clearance Information: K132854

5.5 Intended Use and Indications for Use of the subject device.

The Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are indicated for the correction of ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

The Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens help protect against transmission of harmful UV radiation to the cornea and into the eye.

For Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear, the eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting systems.

5.6 Device Description

The Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are manufactured by using cast molding method. The lens material, polymacon, is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) crosslinked with ethylene glycol dimethacrylate (EGDMA). A UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 5 % in the UVB range of 280 to 315 nm and less than 50 % in the UVA range of 316 to 380 nm.

The lenses are tinted from edge to edge for visibility purposes with the color additive C.I. Reactive Blue No. 4 and printed with an intermittent coating containing a combination of the following approved pigments: Copper Phthalocyanine, Reactive Black 5, Iron Oxide, Titanium Dioxide, Carbazole Violet and D&C Yellow No. 10. The Lenses are available as aspheric lenses. Each finished lens is supplied in a plastic blister container with a sterile isotonic phosphate buffered saline solution containing 0.01 % sodium hyaluronate and 0.1 % trehalose wetting agents.

5.7 Summary of Clinical Study

Polymacon lenses have been used widely. Their safety and effectiveness have been well documented and cleared by FDA. Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (K132854) submitted by Yung Sheng Optical Co., Ltd. is an example.

Clinical studies for the Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are not required for the premarket notification as the USAN name and process are the same as the above mentioned predicate devices.

5.8 Non-clinical Testing

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens. The results of all testing demonstrated that the safety and effectiveness of the Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are equivalent to the Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (K132854). The following tests were conducted as recommended by the FDA Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, February 27, 1997:

- Toxicity
    1. Acute Systemic Injection Study: The lens material meets the requirements of the systemic injection test and is considered non-toxic.
    2. White Rabbit Ocular Irritation Test: Ocular irritation test was performed and produced no ocular irritation.
    3. Cytotoxicity Test: The test article meets the requirements of ISO 10993-5.
- Extractables
- Finished Lens Parameters
- Light Transmittance
- Refractive Index
- Water Content
- Shelf-life
- Mechanical Properties Comparative Testing

- Specific Gravity Comparative Testing
- Physical Compatibility Test with Contact Lens Care Solution and Packaging Solution

The results of the non-clinical testing demonstrated that the Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are substantially equivalent to the predicate device.

5.9 Substantial Equivalence Determination

The Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens submitted in this 510(k) file are substantially equivalent in intended use, technology/principles of operation, materials and performance to the cleared Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear which is the subject of K132854. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Comparison Table			
Item	Eye Secret 38 Color	Eye Secret 38 Color 1-Day	Predicate Device (K132854)
Product Name	Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear	Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear
Regulatory Number	886.5925	886.5925	886.5925
Classification	II	II	II
Intended Use	The same	The same	Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for daily wear for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by person who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
Prescription Use	Yes	Yes	Yes
Material	**polymacon**	**polymacon**	**polymacon**
Manufacturing Method	Cast Molded	Cast Molded	Cast Molded
Water Content	38 %	38 %	38 %
Powers	-0.00 D ~ -20.00 D	-0.00 D ~ -20.00 D	-0.50 D ~ -12.00 D
Light Transmittance	95 % ± 5 %	95 % ± 5 %	95 % ± 5 %
UV-A	< 50 %	< 50 %	< 50 %
UV-B	< 5 %	< 5 %	< 5 %
Refractive Index	1.440 ± 0.005 n_d	1.440 ± 0.005 n_d	1.440 ± 0.005 n_d
Base Curve	8.6 ± 0.2 mm	8.7 ± 0.2 mm	8.6 ± 0.2mm
Diameter	14.0 ± 0.2 mm	14.0 ± 0.2 mm	14.0 ± 0.2mm
Center Thickness	0.06 mm to 0.11 mm (varies with power)	0.06 ± 0.02 mm	0.08 mm to 0.11 mm (varies with power)

5.10 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that the Eye Secret 38 UV Aspheric Color (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear and Eye Secret 38 UV Aspheric Color (polymacon) 1-Day Soft (hydrophilic) Contact Lens are substantially equivalent to the predicate device.